LEISTUNG

MECHANICAL VENTILATOR
PR4 - g
R 04-04 (44) REV. 04

GMP CERTIFICATE
NBR ISO 9001:2008
EN ISO 13485:2003 + AC 2009

PR4-g
PACIENTE
ADULTO
PEDIATRICO
NEONATAL
Selecione e confirme com - ENTER
LEISTUNG
PR4-g
CIRCUITO PACIENTE
VÁLVULA EXALATÓRIA

PR4-g

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ANVISA registry:
Technical Name: Pressure and Volume Lung Ventilator
Commercial Name: Lung Ventilator Leistung PR4-g
ANVISA Registry No.:80203470005

SUMMARY

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GUIDELINES AND DECLARATIONS OF LEISTUNG EQUIPAMENTOS LTDA ABOUT ELECTROMAGNETIC COMPATIBILITY (EMC)

Manufacturer Guidance and Declarations – Electromagnetic Emission		
PR4-gis designated for use in electromagnetic ambience as specified bellow. It is recommended that the PR4-g user ensures it be utilized in such ambience.		
Emission Tests	**Compliance**	**Electromagnetic ambience - guidelines**
RF emissions ABNT NBR IEC CISPR11	Group 1	**Lung ventilator PR4-g** utilizes RF energy only for its internal functions. However, its RF emissions are very low and it is improbable it causes any interference with nearby equipments.
RF emissions ABNT NBR IEC CISPR11	Class A	**Lung ventilator PR4-g** is appropriated for all establishments but domestic and may be used in residential establishments and those directly connected to the public low voltage power distribution that supplies edifications for domestic use.
Harmonic emissions IEC 61000-3-2	Not applicable	
Emissions due to the fluctuation of voltage flicker IEC 61000-3-3	Not applicable	
RF emission CISPR 14-1	Complies	**PR4-g**is not suitable for interconnection with other equipment.
RF emission CISPR 15	Complies	**PR4-g**is not suitable for interconnection with other equipment.

⇒ Para In order to avoid RF interference, the **PR4-g** should not be used stacked on others equipment. If this is required, it is recommended to be observed the normal use of equipments.

Manufacturer Guidance and Declaration – Electromagnetic Immunity
PR4-g is intended for use in environment electromagnetic specified below. It is recommended that the client or user of Lung Ventilator LUFT2-g ensures that it is used in such environment.

Emission tests	Test Level ABNT NBR IEC 60601	Compliance Level	Electromagnetic Environment – Guidances
Electrostatic Discharges (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	Not applicable	Floors should be wood, concrete or ceramic. If the floors are covered with synthetic material, relative humidity should be at least 30%.
Fast Transient Burst ("Burst") IEC 61000-4-4	± 2 kV at power lines ± 1kvat I/O lines	Not applicable	Quality of power supply should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	Not applicable	Quality of power supply should be that of a typical commercial or hospital environment.
Power outage, short interruptions and voltage variations on the lines of power input IEC 61000-4-11	< 5% $\mathbf{U_t}$ (> 95% voltage drop of Ut) by 0.5 cycles. 40% Ut (60% voltage drop of Ut) by 5 cycles 70% Ut (30% voltage drop of Ut) by 25 cycles. < 5% Ut (> 95% voltage drop of Ut) by 5 seconds.	Not applicable	Quality of power supply should be that of a typical commercial or hospital environment.
Magnetic fields at power line frequency	3A/m	Not applicable	Magnetic fields at power supply frequency should be that of a typical commercial or hospital environment.

Manufacturer Guidance and Declaration – Electromagnetic Immunity

The **Lung Ventilator PR4-g** is intended for use in environment electromagnetic specified below.
It is recommended that the client or user of **Lung Ventilator PR4-g** ensures that it is used in such environment.

Immunity tests	Test level ABNT NBR IEC 60601	Compliance level	Electromagnetic Environment – Guidances
			Portable and mobile RF communication equipments must not be used close to any part of the lung ventilator PR4-g, including cables, Recommended separation distance (equation with respect to the transmitter frequency. Recommended separation distance:

RF Conducted IEC 61000-4-6	3 Vrms 150 kHz up to 80 MHz out of the bands[A] ISM 10 Vrms 150 kHz up to 80 MHz within bands[A] ISM	Not Applicable	$d = 1.16\ [\ \boldsymbol{P}\ ]^{½}$ $d = 1.2\ [\ \boldsymbol{P}\ ]^{½}$ $d = 1.2\ [\ \boldsymbol{P}\ ]^{½}$ 80 MHz up to 800 MHz $d = 2.3\ [\ \boldsymbol{P}\ ]^{½}$ 800 MHz up to 2.5 GHz Where ***P*** is the maximum nominal power output of transmitter, in watts (W), according to transmitter manufacturer, and ***d*** is the recommended separation distance, in meters (m). The field intensity established by RF transmitter, as determined by electromagnetic inspection on the local[c] should be less than compliance level in each frequency band [D]. Interference may occur around the equipment marked with this symbol:
RF Radiated IEC 61000-4-3	10 V/m 80 MHz up to 2.5 GHz		

NOTE 1 At 80 MHz and 800 MHz applies the highest range of frequency**.**

NOTE 2 This guidance may be not applicable in all situations. The electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

A The bandwidth ISM (Industry, medical and scientific), between 150 kHz and 80 MHz are 6.765 MHz; 13.553 MHz to 13.564 MHz; 26.957 MHz to 27.283 MHz and 40.66MHz to 40.70MHz.

B The compliance level in the bandwidth ISM between 150KHz and 80MHz and in the frequency range between 80MHz to 2,5GHz, intends to reduce the probability of mobile and portable communication equipments to cause interference if they are inadvertently brought to the patient´s environment. For this reason, an additional factor of 10/3 is used to calculate the recommended separation distance for transmitter in range of frequency.

C The field intensity established by fix transmitters, like base transceiver stations, telephone (cellular and wireless), land mobile radio, amateur radio, AM and FM transmitter and TV transmitter, can´t be predicted theoretically with accuracy. To evaluate the electromagnetic environmental due to RF fix transmitters, it is recommended to consider a local electromagnetic inspection. If the local field intensity where the **Lung Ventilator PR4-g** is located exceeds the above applicable RF compliance level, the **Lung Ventilator PR4-g** should be observed in order to verify the normal operation. If an unusual performance is observed, additional procedure may be necessary, such as reorienting or replacement of **Lung ventilator PR4-g**.

D Above the frequency range of 150kHz, the field intensity should be smaller than (v1) V/m.

Recommended separation distance between portable and mobile RF communication equipments and the Lung Ventilator PR4-g

The **Lung Ventilator PR4-g** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Lung Ventilator PR4-g** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Lung Ventilator PR4-g** recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz out of Bandwidth ISM $d = 1.16\ [\ \boldsymbol{P}\ ]^{½}$	150 kHz up to 80 MHz within bandwidth ISM $d = 1.2\ [\ \boldsymbol{P}\ ]^{½}$	80 MHz up to 800 MHz $d = 1.2\ [\ \boldsymbol{P}\ ]^{½}$	800 MHz up to 2.5GHz

				$d = 2.3\ [\ \boldsymbol{P}\ ]^{1/2}$
0.01	0.11	0.12	0.12	0.23
0.1	0.36	0.37	0.37	0.72
1	1.16	1.2	1.2	2.3
10	3.68	3.79	3.79	7.27
100	11.67	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

NOTE 2 At bandwidth ISM (Industrial, Scientific and Medical), between 150 kHz and 80 Mhz, there are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957MHz to 27.283 MHz and 40.66 MHz to 40,70 MHz.

NOTE 3 An additional margin of 10/3 is used to calculate the separation distance recommended for transmitters in the bandwidth ISM between 150kHz and 80Mhz and the bandwidth 80 MHz to 2.5 GHz to reduce the interference probability from communication mobile equipment could cause if it be carried unwarned in patient area.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CHAPTER 1 – PRESENTATION

In this User Manual, are presented the necessary information for the correct use of the **Lung Ventilator PR4-g.** The indications relating to enforcement and regulations, mentioned in this manual, is a guideline, the physician should adapt, as their criterion, the needs of patients.

GENERAL	
MODEL	**PR4-g**
ANVISA Registry	**No. 80203470005**
MEDICAL DEVICE CLASSIFICATION	**CLASS III**
OPERATION MODE	**Continuous operating**
Classification according to type against electrical shock (insulation).	**CLASS II** **Internally Energized Device**
Classification according to type of protection against electrical shock	**TYPE B**
Level of protection against water penetration	**IPX0**
EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE.	

PHYSICAL CHARACTERISTICS	PARAMETERS	Value
Dimensions (Ventilator)	Height	150 mm
	Width	270 mm
	Depth	230 mm
	Weight	5.20 kg

EXTERNAL ELECTRIC POWER SOURCE	
NOMINAL VOLTAGE	11.5 V up to 15 V
NOMINAL CURRENT	1.90A up to 1.5A
NOMINAL POWER	30 W (Max.)
INPUT FUSE	2.5A/250V 20 mm SB SLOW
REPLACE THE FUSE ONLY WITH OTHER WITH THE SAME CURRENT AND VOLTAGE SPECIFICATIONS.	

INTERNAL ELECTRIC POWER SOURCE		
Nominal Voltage	12 V	
Nominal Capacity	2.2Ah	
Type	VRLA (Sealed, does not emit gas)	
Autonomy	Battery Completely	Minimum of 120 minutes

	Charged 77ºF (25ºC)	autonomy
Capacity affected by temperature	104ºF (40ºC) 77ºF (25ºC) 32ºF (0ºC) 5ºF (-15ºC)	102% 100% 85% 65%
Auto-discharge 68ºF (20ºC)	Capacity after 3 months Capacity after 6 months Capacity after 12 months	90% 80% 60%
Maximum Discharge Current77ºF (25ºC)	48A (5s)	
Charge (Constant Voltage)	Floating 77ºF (25ºC)	13.6 – 13.8V / 1.25A (max).
Charging Time (Battery Discharged)	Vmin=10.5V	4 Hours
Maximum temperature	131ºF (55ºC)	
Internal fuses	2.5A 20 mm SB	

SPECIFICATIONS INFORMED BY BATTERY MANUFACTURER.

THE INTERNAL BATTERY AND FUSE ARE NOT REPLACEABLE BY OPERATOR.

THE SWITCHING FOR INTERNALLY BATTERY OCCURS AUTOMATICALLY WITHOUT THE NECESSITY OF EXTERNAL INTERVENTION, IT DOES NOT INTERFERES THE OPERATION OF THE EQUIPMENT OR THE INSPIRATORY PRESSURE AT OUTPUT PORT TO PATIENT

ENVIRONMENTAL SPECIFICATIONS		VALUES
Environment Temperature	Operation	10ºC up to 35ºC
	Storage – Transport	2ºC up to 40ºC (*)
Relative Humidity	Operation	10% up to 95% Non condensable
	Storage – Transport	0% up to 95% Non condensable
Atmospheric Pressure	Operation	66 – 100 kPa
	Storage – Transport	66 – 100 kPa

PNEUMATIC INPUTS	
OXYGEN	Input DISS 9/16” – 18
PRESSURE	From2.8up to6 kg/cm^2
FLOW	Up to 150 l/min

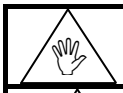
USE ONLY MEDICAL GRADE GAS.

THE MEASURE OF VOLUME AND PRESSURE IS STANDARDIZED BY BAROMETRIC PRESSURE AT SEA LEVEL, BODY TEMPERATURE AND WATER VAPOR SATURATE (BTPS) AND THEY ARE ADJUSTED IN FUNCTION OF ALTITUDE.

(*) The storage of the lung ventilator for long periods at temperature greater than 27ºc, or without electrical connection for periods greater than 2 months, may affect the internally battery life.

WARNINGS, CAUTIONS AND NOTES

WARNINGS

	Constant attention of specialized personnel is required when patient is connected.
	Operation problems require immediate corrective actions.
	The professional in charge of its use should, using your own criterion and knowledge, apply the equipment at patient needs.
	Do not use this equipment in the presence of flammable anesthetic gas mixture, explosion or fire risk.
	Do not use anti-static tubes or electrical conductor in the patient circuit.
	Do not sterilize the equipment with ethylene oxide. There is a high probability to occur irreversible damage in the ventilator components.
	The equipment may be affected by High Frequency Electromagnetic Interference (as cellular, wireless telephone, defibrillators, electro-surgical knifes, magnetic resonance, etc.). Use the tables from Guidance of Electromagnetic Emission and Immunity to determine the correctly separation distances.
	The utilization of accessories and cables that are not specified by LeistungEquipamentosLtda as replacement parts for internal components may result in Emission increase or Immunity reduction of PR4-g.
	Before first utilization and after utilization in each patient, it is necessary clean the ventilator. To sterilize the accessories, follow the instructions on chapter 9.
	When the equipment is not in utilization, close de O_2 cylinder as a safe procedure.

CAUTIONS

	During the warranty period, the stay or movement of equipment should be performed with the original packaging, with its internal correspondent protection, otherwise will result in loss of warranty.
	Never sterilize the ventilator, the internal components is not compatible with sterilization technique.
	Follow the instructions at chapter 9 for equipment cleaning and accessories sterilization.
	Never operate the equipment exposed to direct heat or sunlight.
	Never cover or place the equipment in order to block the air entry for cooling.
	To ensure electrical protections and avoid risk of fire, never change the fuses. If the equipment does not work, contact the Authorized Technical Support**.**

	The improper replacement of the fuses nullifies warranty and represents a risk for the equipment operation, operator and patient safety.

NOTES

	The ventilator is a medical device that has to be operated by qualified and trained people, supervised by a physician.
	When the Lung Ventilator PR4-g is in use, an alternative mean of ventilation should always be available.
	The PR4-g is produced with recyclable materials and should not be thrown into common landfills because it contains toxic materials to nature, for this, contact an authorized dealer.
	Electric Diagrams, Circuitry Diagrams, component list, repair instructions and training can be provided by LeistungEquipamentosLtda, by agreement between the parts.
	LeistungEquipamentos Ltda. is a company of continuous improvement in its products and technical specifications can change without notice.

CHAPTER 2 – INTRODUCTION

The Lung Ventilator PR4-g is micro-controlled and developed within the cut edge technology, and offers a reliable working tool for patient transports that need mechanical ventilation.

The **PR4-g** is easy to operate, because it has an extremely functional designed panel, which permits the operator to use all parameters using few control keys, doing the professional work pleasurable and permits the operator to focus on the patient relationship.

It has anagile and safe patient circuit interconnection system, avoiding any error possibility.

ESPECIFICATIONS

VENTILATION MODES		
PATIENT	**TYPE**	**MODE**
Adult / Pediatric	Assisted / Controlled	Volume Control (VCV)
		Pressure Control (PCV)
	Spontaneous	Pressure Support (PSV)
		Continuous Positive Pressure (CPAP)
	Variables	SIMV (VCV) + PSV
Neonatal	Assisted / Controlled	Continuous Flow
	Spontaneous	Nasal CPAP

SPECIFICATIONS	
Backup ventilation	PCV or VCV in adult and pediatric
FiO_2	50% or 100%
Inspiratory Time	0.3 to 3 seconds
Rise Time	10 to 100 L/min
I:E Ratio	5:1 up to 1:99
Frequency	1 to 150 cycles per minute
Tidal Volume	10 to 1500 ml
Trigger Sensibility	-1.0 up to -10.0 cmH_2O
Control Pressure	2 up to 30 cmH_2O
Support Pressure	2 up to 30 cmH_2O
PEEP	0 up to 20 cmH_2O
Inspiratory Flow	- VCV: Automatic Adjustment - PCV: min 120 L/min - Neonatal Continuous Flow: 5 up to 15 L/min

	- Neonatal Inspiratory Flow: 1 up to 100 L/min
Apnea	10 up to 45 seconds
Inspiratory Pause (VCV Mode)	0.0up to 2.0 seconds
Flow waveform	Descending ramp
Inspiratory pressure inner safety valve	Adjusted in 120 H_2Ocm
Inlet O_2 Pressure Regulator	Internally incorporated into the equipment
STAND BY	To maintain the configuration without cycling
SCALES	Automatic scales adjustment
FREEZE	For graphics analysis
Altitude Compensation	0 up to 6000 m (meters above sea level)
OUTPUT PARAMETER	
INSPIRATORY, PEAK, BASE AND PLATEAU PRESSURE	
INSPIRATORY TIME	
SPONTANEOUS BREATHING I:E RATIO	
TIDALVOLUME	
TOTAL FREQUENCY	
ALL THE INDICATORS IS VISUALIZED ON GRAPHIC DISPLAY	
RESPIRATORY MECHANICS	
AUTOPEEP	
PROGRAMMABLE ALARMS	
MAXIMUM AIRWAY PRESSURE	
MINIMUM AIRWAY PRESSURE	
INSPIRATORY MAXIMUM / MINIMUM TIDAL VOLUME	
APNEA	
MAXIMUM FREQUENCY	
AUTOMATIC ALARMS	
I:E INVERSION	
PEEP	
LOW PRESSURE O_2 GAS INPUT	
INTERRUPTED CYCLE	
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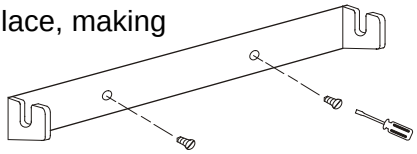
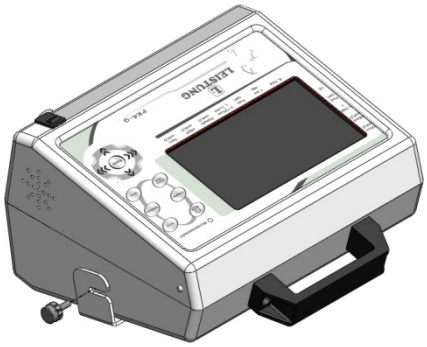
PRESSURE– TIME CURVE	
IMAGE FREEZING	
AUTOMATIC SCALES SELECTION	
OTHER FEATURES	
ALARMS LOG	

CHAPTER 3 – FIXING AND CONNECTIONS

FIXING

To fix the equipment support with two screws in the desired place, making sure that it is really firm.

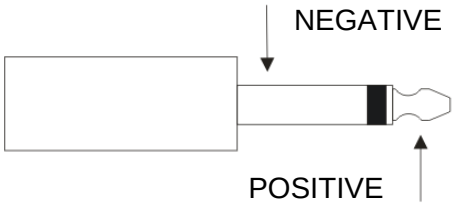


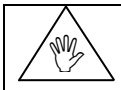


Use the two screws that come laterally in the equipment to fix the equipment at the support.

CONNECTING TO EXTERNAL POWER SOURCE

The electrical connection is in the bottom of the equipment and it has a connector type**Plug** with the polarity indicated as shown in the figure.

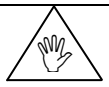


	**VERIFY IF THE CONNECTION OF THE EQUIPMENT IS PROPERLY PERFORMED TO ENSURE A CORRECT OPERATION.**
	VERIFY IF THE JACK IS COINCIDENT WITH THE PLUG BEFORE CONNECTING THE EQUIPMENT.

CONNECTING TO GAS SUPPLY

The pneumatic connection is in the bottom of the equipment.

OXYGEN INLET	Male connector DISS 9/16”-18
OXYGEN CONSUMPTION	3 up to 6 l/ min
	AT THE TIP OF THE PRESSURE TUBE ARE USED CORRESPONDENT FEMALE CONNECTORS
	IT IS POSSIBLE TO USE AS INPUT GAS AIR OR OXYGEN, BUT WHEN AIR IS USED, THE EQUIPMENT WILL HAVE THE FIO_2 FIXED IN 21%.
	THE THREAD CONNECTORS USED IN THE GAS INLET COMPLIES WITH NBR 11906 AND ISO 5359 STANDARD THAT GIVE THE MINIMUM CONDITIONS FOR THIS KIND OF CONNECTORS.
	THE EQUIPMENT GAS INPUT IS MADE WITH A **RETENTION UNIDIRECTIONAL VALVE**, WHICH AVOIDS THE REVERSE FLOW THROUGH INLET PORT.

INPUT PRESSURE	
OXYGEN	2.8 up to 7 kg/cm^2
MINIMUM FLOW PROVISION	60l/min.
MAXIMUM FLOW	150l/min.
	EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC GAS MIXTURE, DANGER OF EXPLOSION OR FIRE.
	IT MUST BE USED AIR AND OXYGEN COMPRESSED, CLEAN AND DRY IN ORDER TO AVOID CONTAMINATION THAT AFFECTS THE EQUIPMENT AND MAY GENERATE A BAD OPERATION.
	THE LUNG VENTILATOR PR4-G HAS AN INTERNAL PRESSURE REGULATOR THAT AVOIDS, FOR THE SPECIFIED PRESSURE RANGE, THE INSPIRATORY PRESSURE LOSSES.

	DO NOT LET THE INLET GAS PRESSURE BE LESS THAN THE LOW SPECIFIED, THIS MAY CAUSE INSPIRATORY PRESSURE REDUCTION AT PATIENT PORT.
	THE LUNG VENTILATOR PR4-G DOES NOT HAVE INTERNAL AIR COMPRESSOR, SO WHEN THE INLET GAS ENDS, THE EQUIPMENT STOPS CYCLING.

BREATHING CIRCUIT

The breathing circuit connection is in the bottom of the equipment.

Use breathing circuitaccording to the patient type: adult, pediatric or neonatal, the difference is on the tube internal diameter.

⚠	IN RESPIRATORY CIRCUITS WHICH HAVE WATER DRAIN IN ITS BRANCHS (INSPIRATORY/EXPIRATORY), VERIFY THE HEMERTICITY TO AVOID VOLUME LEAKAGE IN THE CIRCUIT.
⚠	VERIFY THE CORRECT POSITION OF THE DIAPHRAGM OF THE EXALATORY VALVE. **SEE CHAPTER 8.**

	THE CONNECTORS OF THE PATIENT CIRCUIT ARE CONICAL TYPES 22mm AND THEY ARE ACCORDING WITH THE **ISO 5356-1(NBR13475)** STANDARD, WHICH DETERMINES THE MINIMAL EXIGIBLE CONDITIONS FOR THESE CONNECTOR TYPES.

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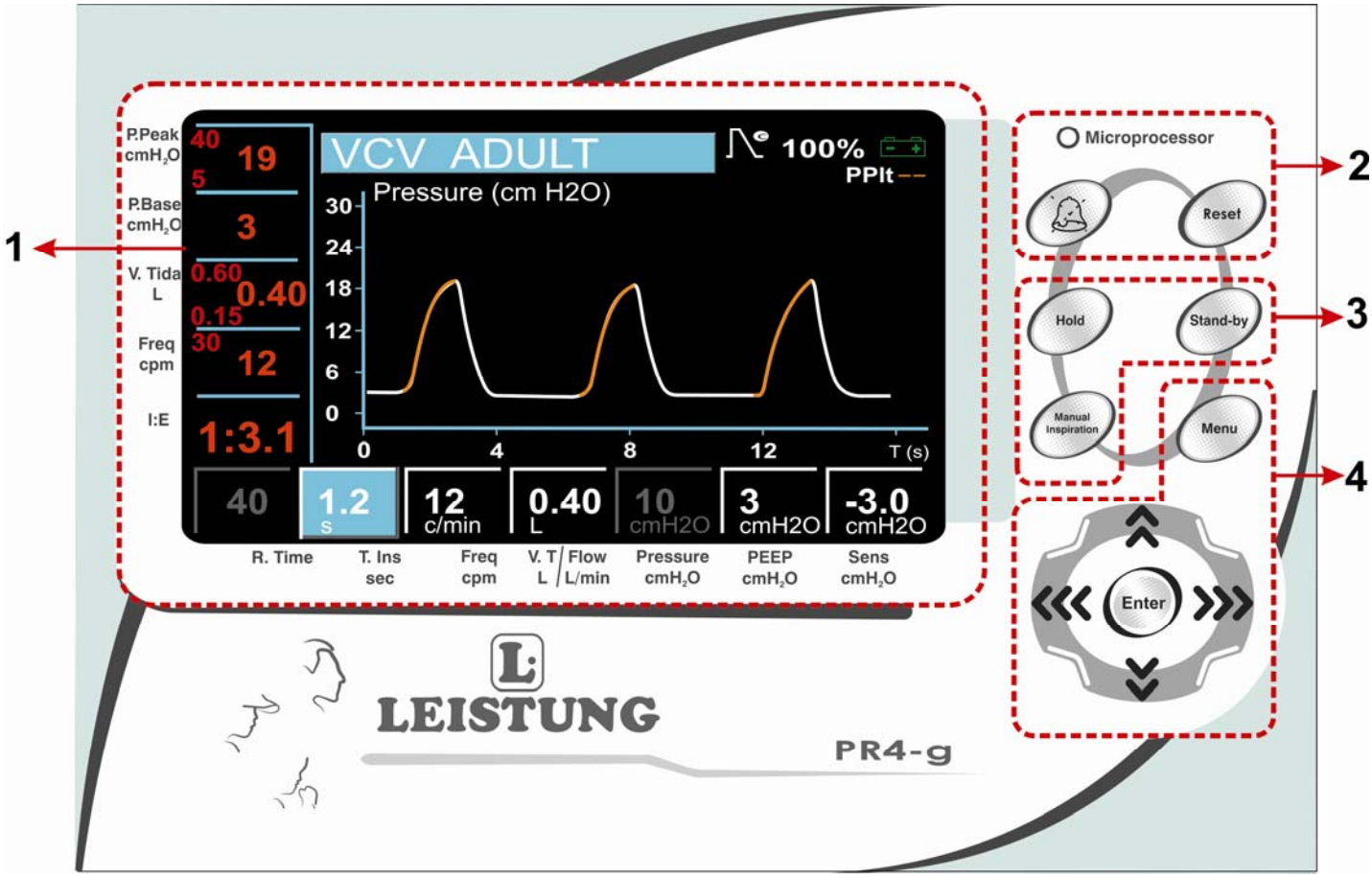
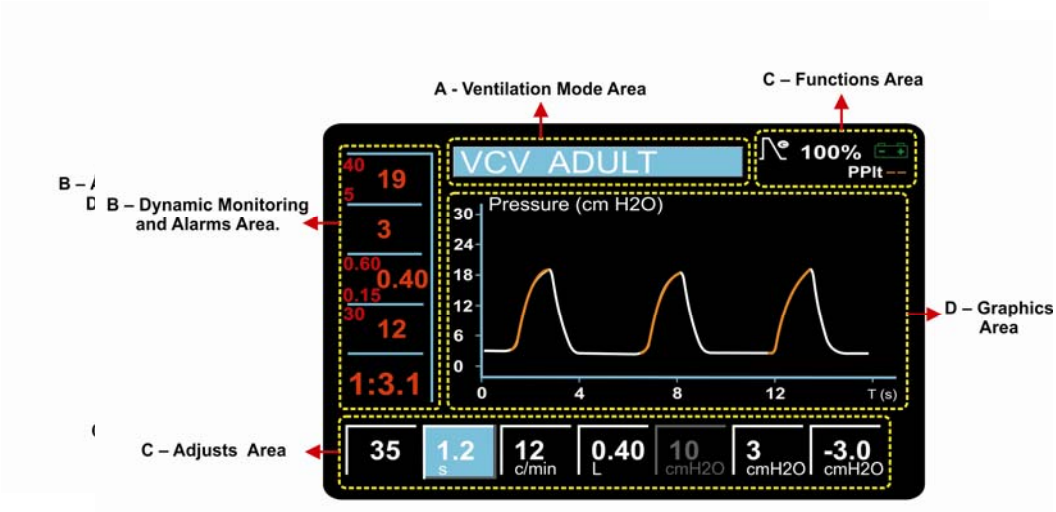
CHAPTER 4 – INDICATORS AND CONTROLS



FRONT PANEL

1- LCD 7”DISPLAY
2- ALARMS
3- DIRECT ACCESS FUNCTIONS
4- CONTROLS AREA



In the LCD 7" graphic screen, it is shown the selected value, curves and resultant values. The screen is distributed in such a way that allows the operator to locate directly the necessary data, offers a high operability level. The screen is distributed in different areas:

A – Ventilation Modes Area

Indicates Ventilation Mode and the patient type (adult. Pediatric or Neonatal) the equipment is operating with.

B – Dynamic Monitoring and Alarms Area.

The parameters resulting from the ventilation can be monitored in a numeric column of orange numbers. The set alarm values appear in red color numbers with smaller font.

The tidal volume information is in red color because it is delivered by ventilator in the inspiratory cycle and it is not measured in the expiratory cycle.

C – Adjusts Area

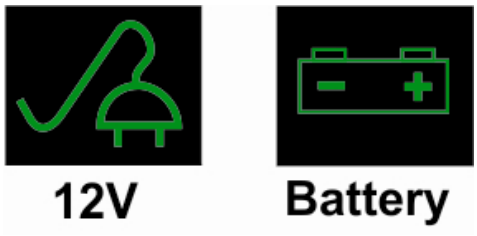
At the bottom of the screen are the operator adjustable parameters, these values are in white color.

D – Function Area

In this area are visualized the functions simbology:

Trigger mode

Oxygen Concentration



Electrical source type (external 12Vdc orinternal battery) the equipment is working with.

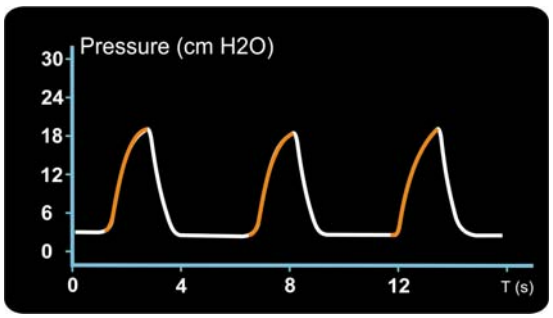
Alarm Silence
It means the alarm was silenced.

Alarms log
Means that there are alarms registered in the historic of the equipment.

Plateau Pressure

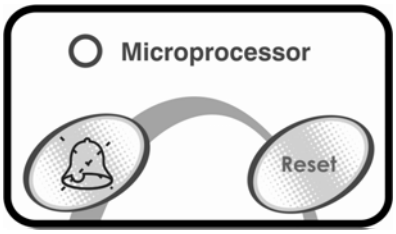
E – Graphics Area

This area shows only one type of curve:



PRESSURE-TIME CURVE
This graphic showsthe occurred changes of airway pressure. The airway pressure is measured in(cmH_2O) and the time is in seconds.

ALARMS



In this section are the keys for Silence or Inactive Alarms, when the Silence key is activated an audio-visual warning is shown on the screen.

Microprocessor Alarm

This alarmis activated in cases of a serious fault that impede the microprocessor to keep the equipment control, when this happens, a light warning is started

and a continuous audible sound at the same time that inactivate the admission gas valves and open the anti-suffocate valves that permits the entrance of environmental air to breathing tubes.

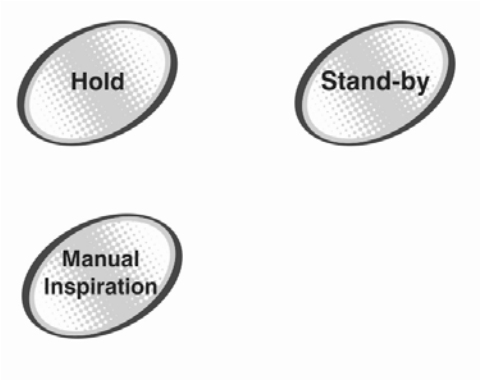
Silence

This key is used to silence audible warnings and do not affect the graphic warning in the equipment screen, this silence is for 30 seconds. Pressing this key twice, the silence period will be 60 second. At the end of this period, if the incident that triggered the alarm on has not been corrected, the alarm restarts.

Reset

This key is used to clean the alarm register (Alarm Historic) and it is also used for cancel non desired adjusts.

DIRECT ACCESS FUNCTIONS

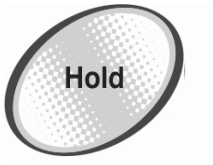


This keypad includes the most frequently used keys.

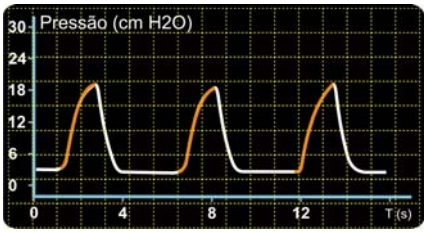
Stand by

Activate the “Stand by” mode, in this mode the ventilator holds the actual parameters configurations and without cycling and no alarms. This “Stand by” mode is shown at screen while it is active.

Freeze



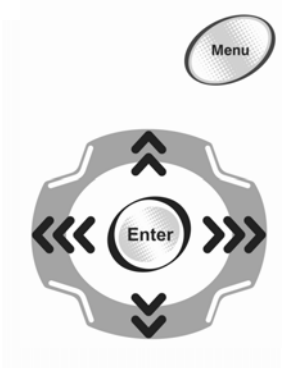
This key freezes the graphic that are in the display, keeping active the patient monitoring.



Manual Inspiration

By pressing this key, the equipment comes into operation with the ventilator mode and last adjusted parameters. Disable “Stand by” mode and starts a new breathing cycle.

CONTROLS AREA



In this sector are the keys that permit to execute the sequence Selection, Adjust and Confirmation and the menu access operations in the graphic screen.

Directional Keys

The directional key permits the operator to move the cursor through the available options at graphic screen and modify the chosen parameter adjusts:

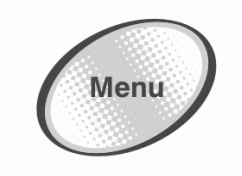
A) Move the selection cursor in the screen in order to select a variable to change.
B)Once selected and accepted by pressing the key “ENTER”, use this to change the selected value.

Vertical selection keys

Change the selected parameter and move the selection cursor via MENU

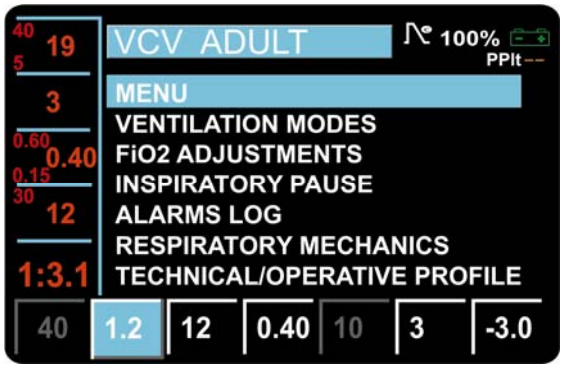
Enter

Access the selected ventilation variable to adjust and confirm or access a MENU function.



Menu

Direct access the ventilator functions MENU.



Pressing

enters in the principal Menu, where there are 6 options.

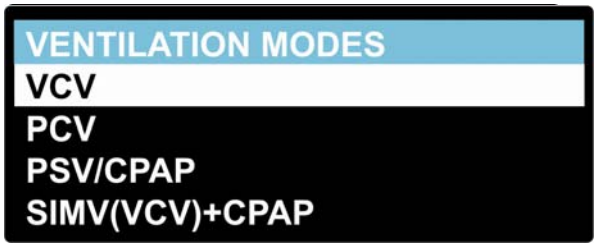
Using the Vertical selection keys, select the desired function.

Pressing

the selected option is accessed.

allows to exit functions menu.
After 12 seconds the ventilatorexit menu automatically.

Ventilation Modes



Shown at the Ventilator Modes graphic screen list.

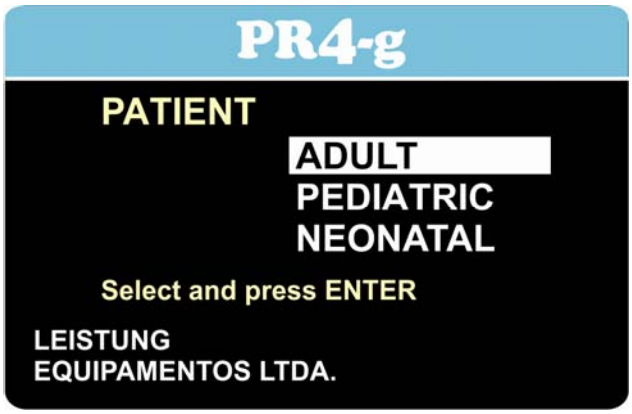
Move the selection cursor and select the desired mode pressing the Enter key.

So, it is shown on the graphical display the values of the new mode to be adjusted and the changing is confirmed by pressing manual inspiration key.

Until the mode is not confirmed, the ventilator will keep working based on the previous mode, maintaining all the previous configuration.

CHAPTER 5 – EQUIPMENT OPERATION START

Upon turning on the equipment the following message is shown, with the patient types to be chosen:



- Adult
- Pediatric
- Neonatal

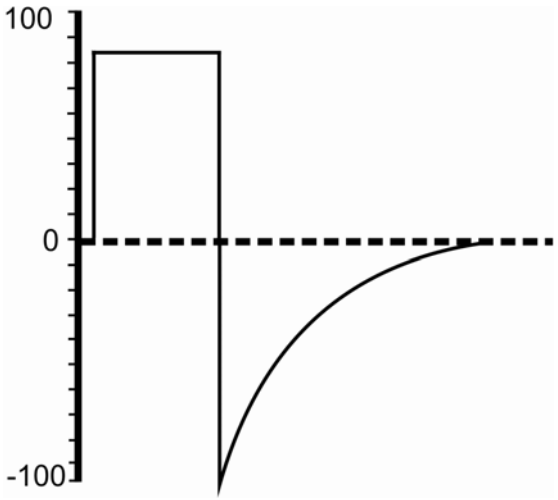
Is considered:
- Adult: Patients who weight is more than 30 kg.
- Pediatric: Patients who weight is between 10 and 30 kg.
- Neonatal: Patients who weight is less than 10 kg.

CHAPTER 6 – VENTILATION MODES

VENTILATION MODES–ADULT AND PEDIATRIC

VCV – Volume Controlled Ventilation

In VCV, PR4-g delivers to patient the programmed tidal volume, integrating the air flow and the inspiration time. Therefore, VCV is flow limited and volume cycled.
PR4-g works with square flow curve in VCV, which accelerates rapidly the flow and maintain it constant during inspiration. This wave pattern allows an appropriate I:E ratio.
As the flow form is square, the volume has a ramp wave and the pressure presents a scale followed by a ramp.

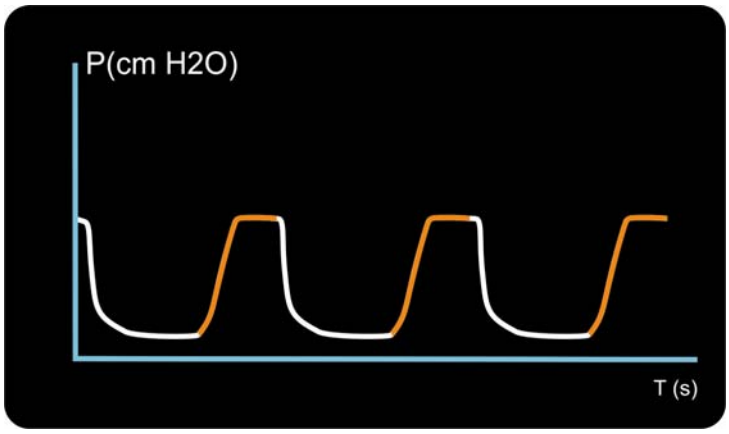


The resultant pressure is free and depends exclusively on physical and mechanical conditions of the respiratory system.
VCV is an assisted/controlled ventilation mode and its inspiratory cycles may be triggered by time or pressure.

In this mode the following variables must be adjusted:

- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Tidal volume (VT);
- PEEP;
- Sensibility (Sens);
- FiO_2.

Inspiratory time



The inspiratory time correspond to the orange color on the graph above.

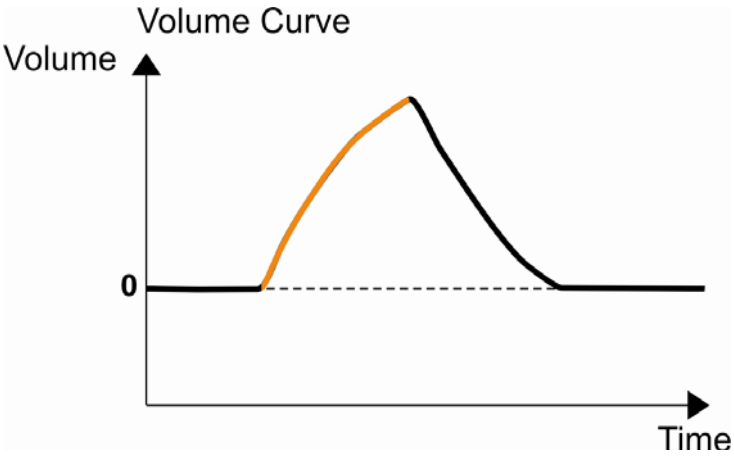
Integrated to current volume, the inspiratory time works as a flow controller, volume cycled, therefore, to perform changes in the velocity of the inspiratory flow the operator must change the variables: inspiratory time and tidal volume.

PR4-g is programmed to cycle by square flow wave form.

Breathing frequency

Refers to ventilation cycles quantity given by PR4-g to patient within the period of one minute.

Tidal Volume



Tidal volume (V Tidal) represents the volume in liters delivered to patient in each ventilation cycle.

PEEP

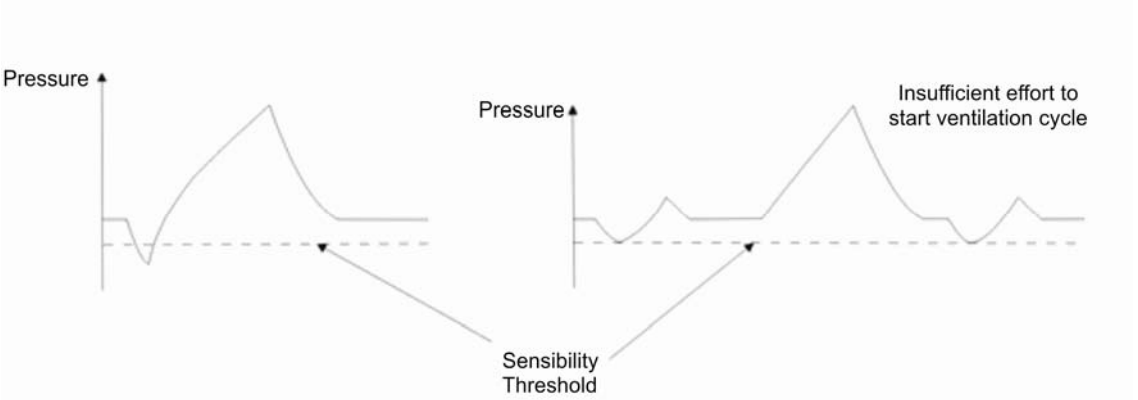
PEEP (Positive End-Expiratory Pressure) is a tool used to recruit and maintain the alveoli open, besides optimizing gases exchanges and to combat lung shunts.

Some pathologies require specific peep values to recruit the alveoli without damaging them.
The use of peep generates hemodynamic repercussions that must be known by the operator.

Sensibility

During artificial ventilation, a pre determined trigger variable must be reached to initiate the inspiration. In VCV the ventilation may be controlled by time, i.e by respiratory frequency, or controlled by the patient himself who triggers the cycles as his necessity.

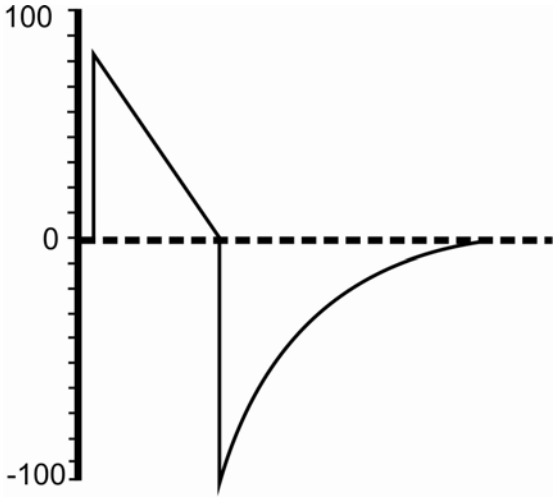
In PR4-g sensibility is triggered by pressure. The ventilator detects a drop in pressure in the airways, which is produced by the patient effort. This effort may initiate the inspiration if the negative pressure performed exceeds the pressure threshold to trigger it or may not start the cycle, if the pressure does not exceed this threshold, generating only breathing work and asynchrony.



The pressure limit is determined by operator, which will indicate always the negative pressure below necessary PEEP value to start ventilating. When this limit is reached, the inspiration valve gets opened and a new ventilation cycle begins.

PCV – PRESSURE CONTROLLED VENTILATION

In PCV the PR4-g delivers to patient the adjusted pressure, the inspiratory flow is automatically adjusted to maintain the pressure constant during the adjusted inspiratory time. Therefore, PCV is pressure limited and time cycled.
PR4-g works with descending flow curve for PCV mode, which starts with its flow in its peak, with progressive reduction of the value along the inspiration. This pattern of wave provides a better distribution of the air in different units of the lung.



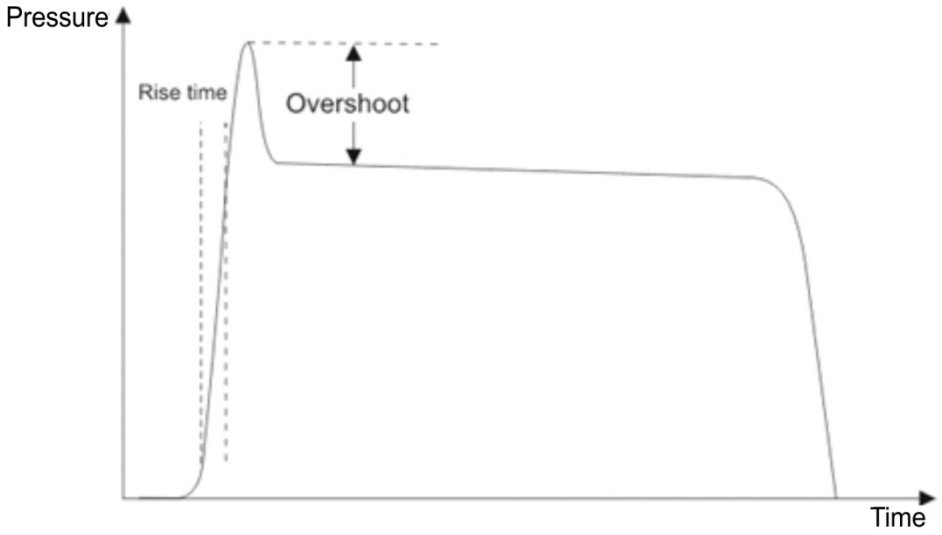
The resultant volume is free and depends only on physical and mechanical conditions of the respiratory system.
PCV is an assisted/controlled ventilation mode and the inspiratory cycles may be triggered by time, flow or pressure.

In this ventilation mode the following variables must be adjusted:

- Rise Time (R. Time);
- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Controlled pressure (Pressure);
- PEEP;
- Sensibility (Sens);
- FiO_2.

Rise Time

Rise Time is the time the ventilator requires reaching the selected pressure. Increase or decrease this time may assist in the comfort of the patient.
In LUFT2-g the Rise Time is modulated by flow, i.e the higher the rise time, the shorter the time to reach the adjusted pressure and the shorter the rise time, the longer the time to reach the selected pressure.
For an appropriate ventilation, the rise time must be adjusted in order to provide the smallest overshoot possible.

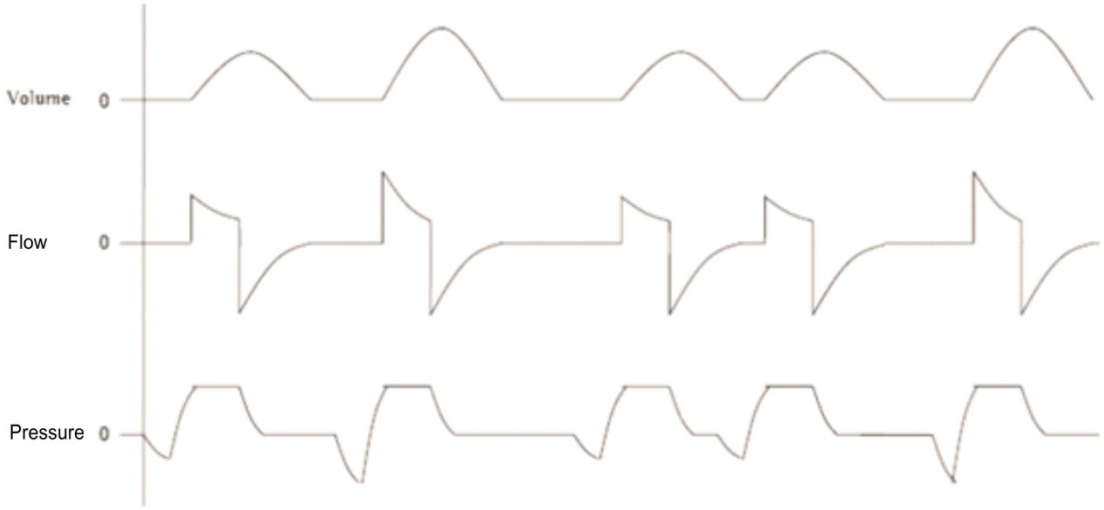


Controlled Pressure

In PCV, the airway pressure level is the main parameter to be adjusted, because it will have a direct influence over the tidal volume available for the patient.
To adjust the controlled pressure you must remind that “Pressure” adjustment refers to pressure value over established value for PEEP.

PSV/CPAP – PRESSURE SUPPORT VENTILATION OR CONTINUOUS POSITIVE PRESSURE

Spontaneous ventilation mode, i.e., triggered and cycled by patient, which the ventilator assists the ventilation through a pre-determined positive pressure maintenance. It allows the patient to control the respiratory frequency and the inspiration time, thus, the inspired air volume. Therefore, the tidal volume depends on inspiration effort, on pre-established pressure support and on respiratory system mechanics.
To perform this function, the ventilator upon starting ventilating, increase the pressure in the circuit for a pre-determined pressure level, providing an additional gas flow. Pressure level is maintained constant during whole inspiration by and flow continuous self-adjustment, which decelerates at the same proportion the pressure in insufflated lung parenchyma increases progressively. The inspiration end occurs when the inspiration flow, upon reduction, reaches a critical value, pre-determined for PR4-g in 25% of peak flow. At this moment occurs the cycling which is determined by flow.



The control variable in this mode is Pressure (Pressure Support) and the tidal volume (VT) is free. The volume variation depends on patient physical conditions and this will be proportional to patient inspiration effort and on adjusted configured support pressure.

The following variables must be adjusted in this ventilation mode:

- Rise Time (R. Time);
- Pressure Support (Pressure);
- PEEP;
- Sensibility (Sens);
- FiO_2.

For safety, the lung ventilator PR4-g goes to expiratory phase if inspiration time is bigger than 3 seconds, or inspiration pressure reaches 10 cmH_2O above expected peak pressure.

Pressure Support

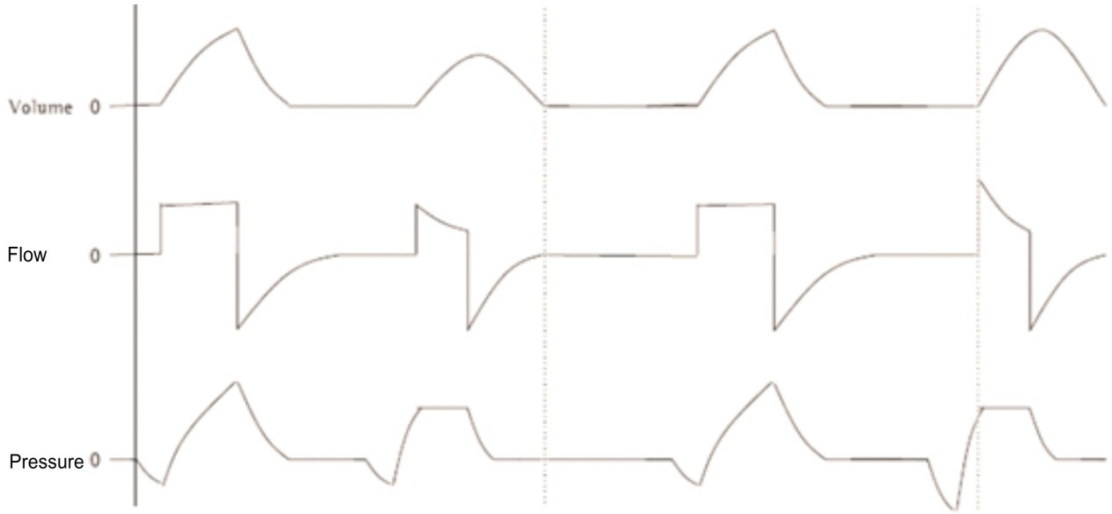
In PSV mode, pressure level in airway is the main parameter to be adjusted because it will directly affect the tidal volume received by patient.
To adjust pressure support it must be remembered that “Pressure” adjustment refers to pressure support value above configured value for PEEP.

CPAP mode is activated when offered Pressure Support is reduced to the maximum.

SIMV (VCV) + PSV - SYNCHRONIZED INTERMITENT MANDATORY VENTILATION BY PRESSURE WITH PRESSURE SUPPORT

Provides the combination of synchronized mandatory ventilation with assisted spontaneous ventilation through pre-configured support pressure, i.e., allow starting weaning process.

This mode has the function of to decrease mandatory ventilations quantity and to allow the patient to make spontaneous ventilations between each cycle, synchronizing the beginning of mandatory cycle with the inspiration effort of the patient.



The following variables must be adjusted in this ventilation mode:

- Rise Time (R. Time);
- Inspiration time(T. Ins);
- Respiratory frequency(Freq);
- Tidal volume (VT);
- Support pressure (Pressure);
- PEEP;
- Sensibility (Sens);
- FiO_2.

Backup Ventilation

Backup ventilation (Backup) is activated in spontaneous ventilation modes. In the lung ventilator PR4-g backup is available in the modes SIMV (VCV) + PSV and PSV/CPAP.

When the selected ventilation mode is SIMV (VCV) + PSV, the ventilator will provide the option to use backup ventilation. After selecting the mode SIMV (VCV) + PSV appears on the screen the option Backup Ventilation. To enable backup ventilation it must be pressed ENTER on YES option. To disable backup ventilation you must move the cursor vertically, select NO and then press ENTER.

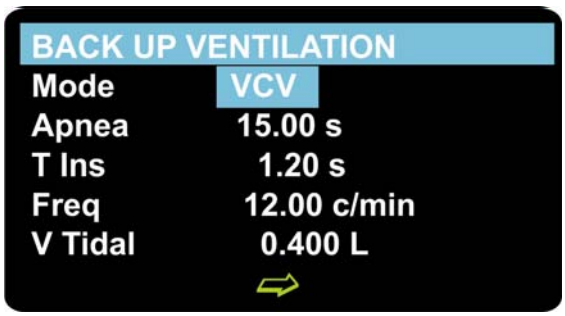
If the selected ventilation mode is PSV/CPAP, the ventilator goes to Backup Ventilation screen and asks for configuration of the following parameters:

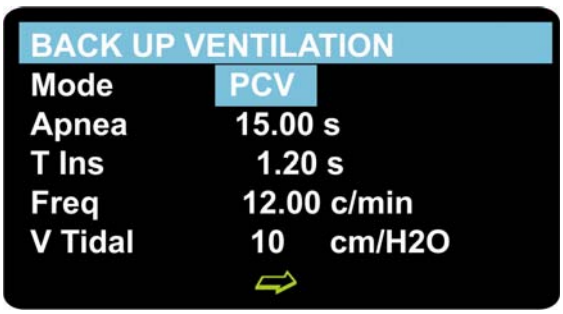
- Mode;
- Apnea;
- Inspiration Time;
- Respiratory Frequency;
- Tidal Volume or Controlled Pressure.

To start working in spontaneous mode the operator must accept all the Backup ventilation programming, pressing ENTER key on the “green arrow” in configuration screen. In case of not accepting or pressing RESET the ventilator returns to its previous mode.

Backup ventilation mode exit is automatic if the patient retakes spontaneous ventilation, ormanual if the operator selects some assisted/controlled ventilation mode.

Ventilation mode





Refers to the selected mode to cycle during the period of backup ventilation. You can choose between VCV and PCV.

Apnea Time

Apnea is the period without spontaneous breathing. Apnea time is the maximum duration the ventilator waits before triggering audiovisual alarm of apnea, starting backup ventilation.

Cycling variables

For backup ventilation configuration you must set the following variables: Inspiration Time, Respiratory Frequency, Tidal Volume (V Tidal) and Controlled Pressure (P con).

	Tidal Volume adjustment will be available when selected VCV and P Con will be available when selected PCV.

PEEP

PEEP level during backup ventilation will be the same as configured in spontaneous modality.

	Apnea time is not available in controlled modes VCV and PCV.
	The ventilator never stops working during modes switch.
	If you do not want to change ventilation mode of the equipment, you must press “RESET” key to cancel the operation.

NEONATAL VENTILATION MODES

Continuous Flow

This is a ventilation mode with continuous flow, time cycled and pressure limited.

In this mode mandatory cycles are provided to patient, however, between each mandatory cycle the patient can breathe spontaneously due to continuous flow presence.

In this ventilation mode the following variables must be adjusted:

- Inspiration Time (T. Ins);
- Respiratory Frequency(Freq);
- Continuous Flow (Flow);
- Controlled Pressure (Pressure);
- PEEP;
- Sensibility (Sens);
- FiO_2.

NASAL CPAP – CONTINUOUS POSITIVE PRESSURE VENTILATION

Nasal CPAP is a spontaneous ventilation mode which allows operator to provide pressure and flow continuous and constant in patient circuit.

This mode may be applied in neonatology and may be offered to patient through cannulas or nasal prongs.

In this ventilation mode the following variables must be adjusted:

- Continuous flow (Flow);
- PEEP;
- FiO_2.

CHAPTER 7 – ALARMS

The alarms are used to monitor the relation between the patient and the machine, activating when, for some reason, some parameter exceeds values set up by the operator, creating a risk to the patient.
The purpose of this chapter is to define the alarms category, visual indicators and the level of urgency for operator response.

The operator can silence momentarily all alarms, keeping the visual indicator.

If during this time, a new or different alarm condition happens, the alarm will be activated and Silence will be canceled.

COLORS AND MEANINGS OF GRAPHICAL INDICATORS

These signals are developed in compliance with valid standards in order to be immediately recognized by the operator that should act to solve the cause. The alarm indication as Warning or Danger to Patient is a Leistung criterion and serves only as orientation, the operator should adapt as his own criterion the patient needs.

COLOR	MEANING
RED	Danger! An operator action is immediately necessary.
YELLOW	Warning! An operator action is needed.

When changing the Ventilation Mode, all alarms registry are cleared, but the Alarm Historic is hold.

HIGH PRIORITY ALARM CONDITION

MAXIMUM INSPIRATORY PRESSURE

This alarm is activated if the airway pressure exceeds the established value in Maximum Pressure Limit control. Audiovisual indication of High Inspiratory Pressure is activated. If the cause is resolved, the sound is deactivated and the visual indicator of new alarm register remains on the screen until it is cleared by pressing RESET. This alarm can be silenced.

MINIMUM INSPIRATORY PRESSURE

This alarm is activated if at the end of the inspiration the airway pressure did not reach a minimum value adjusted in Low Inspiratory Pressure. Audiovisual indication of Low Inspiratory Pressure is activated. If the cause is resolved, the sound is deactivated and the visual

indicator of new alarm register remains on the screen until it is cleared by pressing RESET. This alarm can be silenced.

APNEA ALARM

This alarm is activated if the time between two consecutive inspiratory efforts to start the ventilator is longer than the established period of apnea. Audiovisual indication of Apnea is activated. If the patient makes two consecutive breathings, i.e. resuming spontaneous ventilation mode, the sound is deactivated and the visual indicator of new alarm register remains on the screen until it is cleared by pressing RESET. This alarm can be silenced.

INTERRUPTED CYCLE

Available only on pressure controlled modes (PCV and PSV). It is activated if the inspiration is interrupted by pressure limit variable, indicating to the user the possible cause which may be high Rise Time or airway obstruction.
The purpose of this alarm is to prevent hypoventilation or possible bad patient adaptation.

OXYGEN LOW PRESSURE

When the inlet gas pressure is less than 2,8kg/cm^2 this alarm is activated and deactivated when the inlet pressure is reestablished. This alarm cannot be canceled or adjusted, but it is possible to silence it with silence key.

MICROPROCESSOR

This alarm is activated if a failure occurs which blocks the equipment to control the equipment.A light warning (LED) is activated on the panel and a sound alarm too. The valves that provide air to the patient are deactivated and anti-suffocation valve is enabled.

LOW PRIORITY ALARM CONDITION

MAXIMUM TIDAL VOLUME

This alarm is activated if the tidal volume delivered by the ventilator is greater than the maximum adjusted value for more than three cycles. Audiovisual indication of maximum tidal volume is activated. If the cause is resolved, the sound is deactivated and the visual indicator of new alarm register remains on the screen until it is cleared by pressing RESET.

MINIMUM TIDAL VOLUME

This alarm is activated if the tidal volume delivered by the ventilator is lesser than the maximum adjusted value for more than three cycles. Audiovisual indication of maximum tidal

volume is activated. If the cause is resolved, the sound is deactivated and the visual indicator of new alarm register remains on the screen until it is cleared by pressing RESET.

MAXIMUM RESPIRATORY FREQUENCY

It is activated if the resultant frequency is higher than the fixed value in alarm. Audiovisual indication of maximum frequency is activated. If the cause is resolved, the sound is deactivated and the visual indicator of new alarm register remains on the screen until it is cleared by pressing RESET.

PEEP ALARM

This alarm is activated if PEEP is different in ± 4cmH_2O of the adjusted PEEP.Audiovisual indication of maximum frequency is activated. If the cause is resolved, the sound is deactivated and the visual indicator of new alarm register remains on the screen until it is cleared by pressing RESET.

PEEP alarm is activated for pressures over and lower than the adjusted PEEP pressure.		
DEFAULT ALARMS CONFIGURATION		
ADULT	MODES: VCV , PCV, PSVand SIMV	P max = 40 cmH_2O; P min = 05 cmH_2O; Vol max = 0.600 L; Vol min = 0.150 L; Freq. = 30cpm;
PEDIATRIC	MODES: VCV , PCV, PSV and SIMV	P max = 30 cmH_2O; P min = 05 cmH_2O; Vol max = 0.400 L; Vol min = 0.050 L; Freq. = 30 cpm;
NEONATAL	MODES: CONTINUOUS FLOW	P max = 20 cmH_2O; P min = 03 cmH_2O; Freq. = 40 cpm;
- DEFAULT ALARMS CONFIGURATION IS ADJUSTED DURING THE EQUIPMENT INITIALIZATION AND IT REFERS TO A MEAN VALUE OF ADJUSTMENT RANGE AJUSTE. - THE PARAMETERS ADJUSTMENTS MUST BE DONE BY THE OPERATOR, CONSIDERING INDIVIDUALLY EACH CLINIC CASE.		
-IT IS RECOMMENDABLE TO BE VERIFIED BY THE OPERATOR THE LIST OF VERIFICATIONS OF THE ALARMS VALUE, ESPECIALLY IN EVENTUAL OPERATOR SWITCH		
- AFTER TOTALLY ENERGY / BATTERY LOSS AND FURTHER RETURN, THE EQUIPMENT RESTARTS WITH ITS DEFAULT ALARMS CONFIGURATION		

ALARMS VALUES VERIFICATION LIST		
PATIENT	**OPERATION MODE**	**CHECK**
ADULT	MODES: VCV , PCV, PSV and SIMV	P max P min Vol max Vol min Freq.
PEDIATRIC	MODES: VCV , PCV, PSV and SIMV	P max P min Vol max Vol min Freq.
NEONATAL	MODES: CONTINUOUS FLOW	P max P min Freq.

TESTE DE INTEGRIDADE DO SISTEMA DE ALARMES

1 – Using a test balloon connected to equipment, in **"VCV"** mode, in the alarms adjustments setup, adjust **Pmax Alarm** to a value lesser than shownin peak airway pressure value in display. The Maximum Pressure Alarm will start.

2 – Adjust the **Pmin Alarm** to a value greater than the Peak airway pressure value shown in display and disconnect the test balloon, the alarm will start.

3 – Adjust the **MinimumTidal Vol. Alarm** to a greater value than shown at "**Vt**", the alarm will start.

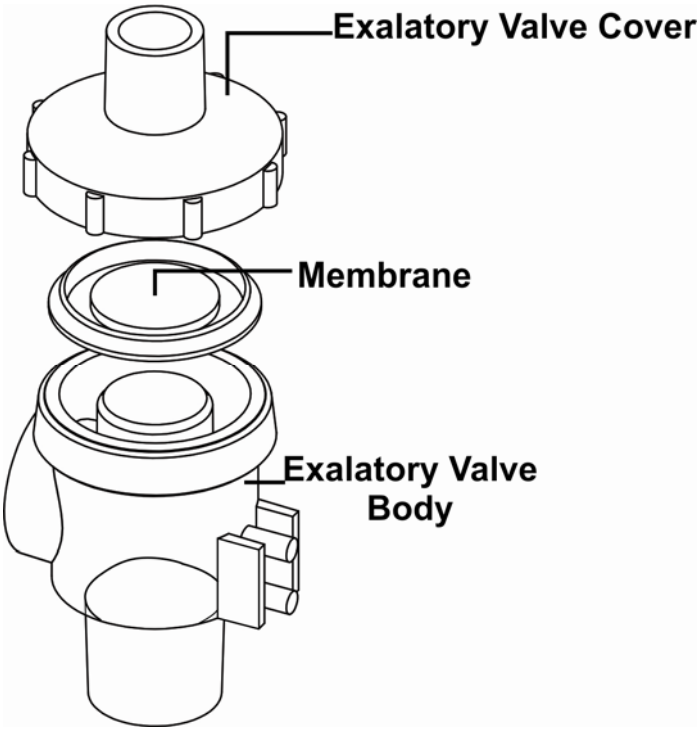
4 – Adjust the **Maximum Tidal Vol. Alarm** to a lower value than shown at "**Vt**", the alarm will start.

5 – Adjust **Freq alarm** to a value lower than shown on screen, maximum freq. alarm will start.

6 –Disconnect the oxygen hose from the high pressure inlet gas. It must activate inlet low pressure alarm.

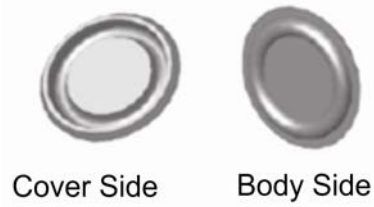
	- EACH TEST IS INDEPENDENT AND CAN BE TESTED OUT OF THIS ORDER. - THE TIME BETWEEN THE ADJUSTMENT AND THE ALARM ACTIVATION CAN VARY IN EACH TEST.
	- IT IS RECOMMENDED THESE TESTS TO BE EXECUTED DURING THE PREVENTIVE MAINTENANCE.

CHAPTER 8 – EXHALATION VALVE ASSEMBLY



DIAPHRAGM POSITION

To ensure a correct work of expiratory valve, assembly the diaphragm as indicated below.



⚠	WHEN ADDED COMPONENTS TO BREATHING TUBES, THE PRESSURE GRADIENT THROUGH LUNG VENTILATOR RESPIRATORY SYSTEM, MEASURED AGAINST PATIENT CONNECTION PORT, MAY INCREASE.
⚠	THE DIAPHRAGM MUST LEAN AGAINST THE COVER OF THE VALVE, FIRST PUT THE DIAPHRAGM ON THE COVER AND ENSURE THAT IT IS WELL PUT, ONLY THEN SCREW THE COVER ON THE VALVES BODY.
⚠	AT THE END OF THREADING, DO NOT MAKE STRONG ADJUSTMENTS.
⚠	THE PATIENT CIRCUIT B TYPE IS MADE WITH CERTIFIED MATERIAL THAT ENSURES THE BIOCOMPATIBILITY OF THIS MATERIAL. CERTIFICATE COPY CAN BE REQUESTED DIRECTLY FROM MANUFACTURER
✎	THE PATIENT CIRCUIT CONNECTOR COMPLIES WITH THE STANDARD NBR 13476.

CHAPTER 9 – CLEANING,DESINFECTION AND STERILIZATION

The parts in contact with the patient may be completely sterilized.

The protocols which define the methods and the frequency must be adapted to the procedure of decontamination and cleaning, here indicated as a guide.

The patient circuit and its parts must be replaced with sterilized or disinfected elements.

Once disconnected from equipment, the patient circuitmust be dismounted in order to clean all parts (remove blood and other wastes). The indicated methods for disinfections must take care to the thermo sensibility of the components.

For equipments with PVC patient circuit is suggested:

- Ethylene Oxide – 55%
- Glutaraldehyde
- Peracetic acid

For equipments with silicon patient circuit:

- Ethylene oxide – 55%
- Glutaraldehyde
- Peracetic acid
- Auto Clave – 121º C psg – 15 minutes. Only for exhalation valve.

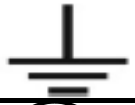
⚠	ETHYLENE OXIDE IS TOXIC, ALL COMPONENTS SHOULD BE PREVIOUSLY DRY BEFORE STERILIZATION, SHOULD BE VENTILATED IN ORDER TO RELEASE THE RESIDUAL GAS, FOLLOW THE MANUFACTURER INSTRUCTIONS.
⚠	THE EXPIRATORY VALVE ACCEPTS ALL METHODS DESCRIBED.
⚠	FOR THE PATIENT CIRCUIT, CONSULT MANUFACTURER RECOMMENDATIONS.
⚠	AVOID THE USE OF PURE ALCOHOL, CLEANSING SOLUTIONS WHICH CONTAIN SOLVENTS, ACETONE, CHLORINATED SUBSTANCES OR CHLOROFORM FOR CLEANING OF THE RESPIRATORY TUBES AND PLASTIC PARTS.

	WHEN AUTOCLAVE THE BREATHING TUBES, THE TEMPERATURE SHOULD NOT PASS THE DESCRIBED VALUE IN ORDER TO AVOID CIRCUIT DAMAGE.

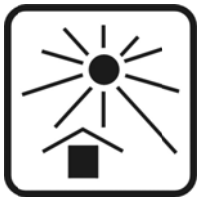
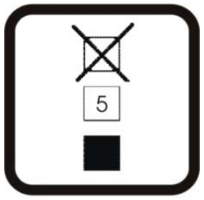
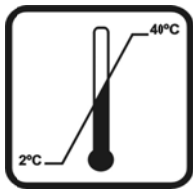
	THE USE OF ETHYLENE OXYDE MAY ACCELERATES THE APPEARING OF GUMS OR ITS DERIVATIVES.
	THE VENTILATOR (ITS CASE) MUST NEITHER BE CLEANED WITH ETHYLENE OXIDE NOR IN AUTOCLAVE.

CHAPTER 10 – SYMBOLOGY

1 - Meaning of the standardized symbols, printed on the equipment, internal and external.

Symbol	Standard	Description
	IEC 60601-1:1994 Symbol No.417-5032	Alternated Current
	IEC 60601-1:1994 Symbol No.417-5031	Continuous Current
	IEC 60601-1:1994 Symbol No.417-5017	Functional Ground Terminal
	IEC 60601-1:1994 Symbol No.417-5019	Protection Ground Terminal
	IEC 60601-1:1994 Symbol No.348	Warning! Consult accompanying documents.
	IEC 60601-1:1994 Symbol No.417-5007	ON (Connected to a internal / external power source)
	IEC 60601-1:1994 Symbol No.417-5008	OFF (Disconnected from internal / external power source)
	IEC 60601-1:1994 Symbol No.878-02-02	B Type Equipment
	IEC 60601-1:1994 Symbol No.417-5172	Class II Equipment
	IEC 60601-1:1994 Symbol No.878-03-01	Electrical Shock Hazard
	IEC 417 Symbol No.5016	Fuse
	ISO 15223:2000 Symbol No.3.3	Consult Accompanying Documents

2 – Meaning of the standardized symbols, printed on the equipment package:

Symbol	Standard	Description
	ISO 780:1997 (E) No. 1	FRAGILE Handle carefully
	ISO 780:1997 (E) No. 3	THIS SIDE UP Indicates the up side of the package
	ISO 780:1997 (E) No. 4	PROTECT AGAINST SUNLIGHT The package must be kept out of direct sunlight
	ISO 780:1997 (E) No. 6	PROTECT AGAINST RAIN The package must be kept out of rain
	ISO 780:1997 (E) No. 14	MAXIMUM STACKING UP Indicates the maximum number of packages can be stacked up for transport and storage
	ISO 780:1997 (E) No. 17	TEMPERATURE LIMIT Indicates the limit temperature for storage and manipulation of the package

3 – Meaning of symbols, printed in this user manual:

Symbol	Standard	Description
	----------	**WARNING!** Condition before which there is the possibility to cause damage to operator or others.
	IEC 60601-1:1994 Symbol No.348	**ATTENTION** Condition before which there is the possibility to cause damage the equipment, its accessories or others.
	----------	**NOTE** Specifies important observations which need to be considered for a correct use of the equipment.
	AN 980	**MANUFACTURER**

CHAPTER 11 – ACCESSORIES

DESCRIPTION	FUNCTION
PATIENT CIRCUIT	PATIENT-EQUIPMENT INTERFACE **NOTE:**ONLY THE MODEL INCLUDED WITH THE EQUIPMENT MUST BE USED
SUPPORT SHAPE FOR FIXING	TO FIX THE EQUIPMENT IN THE MOBILE UNIT
O_2 GAS INLET HOSE	O_2GAS INLET
USER MANUAL	INFORMATION ABOUT OPERATION, REQUIREMENTS AND FUNCTIONS OF THE EQUIPMENT
EXHALATION VALVE	PATIENT BREATHING CONTROL
DC POWER INPUT CABLE	CABLE FOR CONNECTION TO THE EQUIPMENT POWER SUPPLY **NOTE:**THE VALUES OF ELECTRICAL POWER DESCRIBED IN THIS MANUNAL MUST BE RESPECTED

Illustrative photos only

THE UTILIZATION OF ACCESSORIES AND CABLES WHICH ARE NOT SPECIFIED BY LEISTUNG EQUIPMENTS LTDA. MAY RESULT IN ELECTROMAGNETIC EMISSION INCREASING OR IMMUNITY REDUCTION OF THE EQUIPMENT.

CHAPTER 12 – PREVENTIVE MAINTENANCE

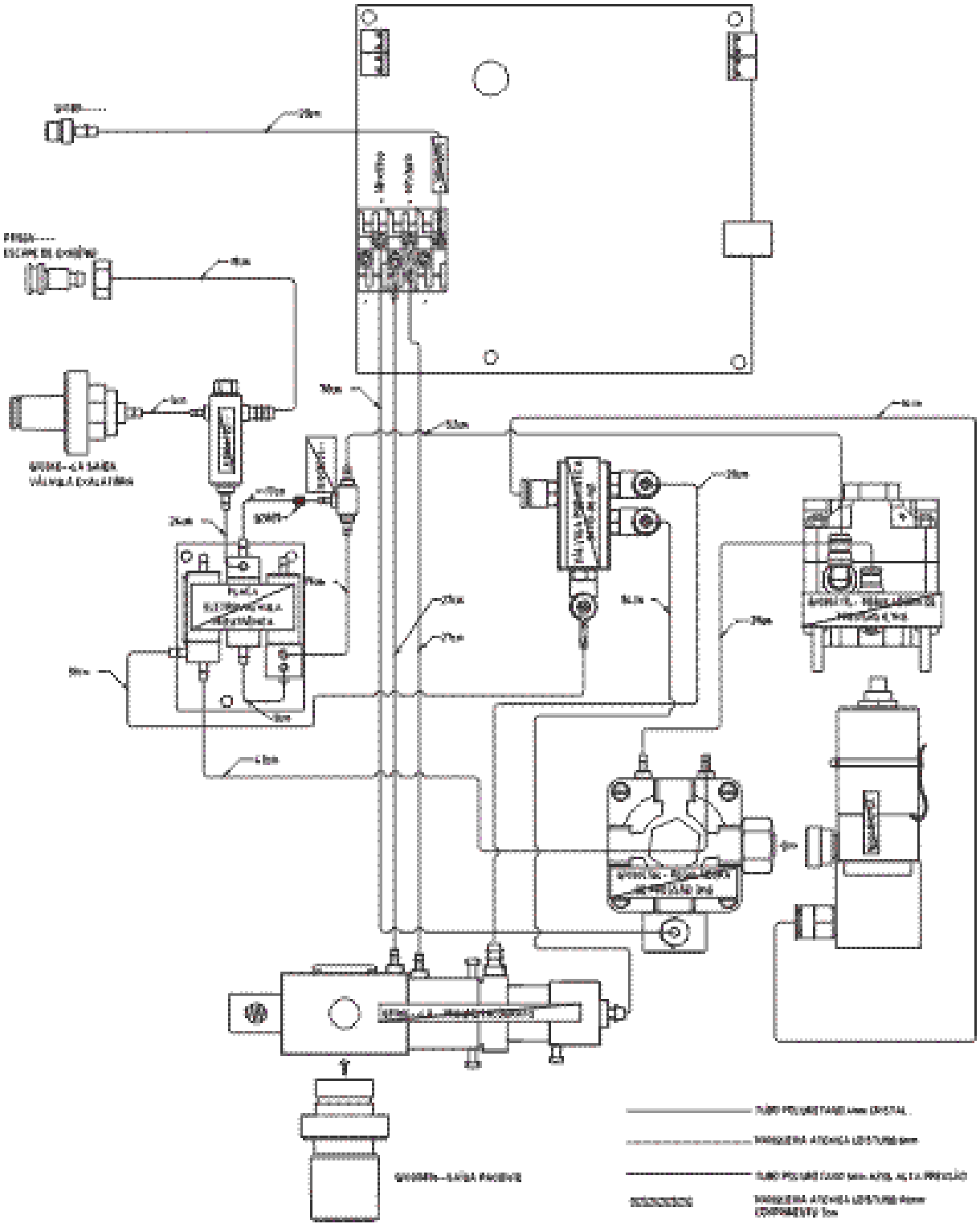
It is mandatory to be performed a preventive maintenance respecting the following chronogram.

Maintenance	Hours of use
1st	1500 hours
2nd	3000 hours
3rd	5000 hours
4th	7000 hours
5th	9000 hours

	MAINTENANCE MUST BE DONE BY QUALIFIED PERSONNEL AND RESPECTING THE ACCORDING PROTOCOLS.
	THE MANUFACTURER IS NOT RESPONSIBLE FOR NORMAL OR SPECIAL DAMAGE DUE TO BAD USE.

	IT IS RECOMMENDED TO CHANGE THE INTERNAL BATTERY EVERY FOUR YEARS.
	ALLWAYS BEFORE USING THE EQUIPMENT, CHECK THE BATTERY INTEGRITY, MAKING THE EQUIPMENT TO WORK WITHOUT EXTERNAL POWER SUPPLY.
	IT IS RECOMMENDED TO BE DONE A VERIFICATION OF THE VENTILATION PARAMETERS OF PR4-G EVERY YEAR, USING CERTIFIED MEASURE PATTERNS.

CHAPTER 13 – PNEUMATIC DIAGRAM



CHAPTER 14 –*RADFORD*TABLE

TABLE USED TO FIND THE FREQUENCY ACCORDING TO PATIENT WEIGHT IN YOUNGS AND ADULTS

		FREQUENCY													
kg	**GENDER**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**25**
40	M				X	X	X	X	X	X	X	X	X	X	X
40	F				X	X	X	X	X	X	X	X	X	X	X
45	M				X	X	X	X	X	X	X	X	X	X	X
45	F				X	X	X	X	X	X	X	X	X	X	X
50	M	X	X	X	X	X	X	X	X	X	X	X	X	X	
50	F	X	X	X	X	X	X	X	X	X	X	X	X	X	
55	M	X	X	X	X	X	X	X	X	X	X	X			
55	F	X	X	X	X	X	X	X	X	X	X	X			
60	M	X	X	X	X	X	X	X	X	X	X	X			
60	F	X	X	X	X	X	X	X	X	X	X	X			
65	M	X	X	X	X	X	X	X	X	X	X	X			
65	F	X	X	X	X	X	X	X	X	X	X	X			
70	M	X	X	X	X	X	X	X	X	X	X	X			
70	F	X	X	X	X	X	X	X	X	X	X	X			
75	M	X	X	X	X	X	X	X	X	X	X	X			
75	F	X	X	X	X	X	X	X	X	X	X	X			
80	M	X	X	X	X	X	X	X	X	X	X	X			
80	F	X	X	X	X	X	X	X	X	X	X	X			
85	M	X	X	X	X	X	X	X	X	X	X	X			
85	F	X	X	X	X	X	X	X	X	X	X	X			
90	M	X	X	X	X	X	X	X	X	X	X	X			
90	F	X	X	X	X	X	X	X	X	X	X	X			
100	M	X	X	X	X	X	X	X	X	X	X	X			
100	F	X	X	X	X	X	X	X	X	X	X	X			
110	M	X	X	X	X	X	X	X	X	X	X	X			
110	F	X	X	X	X	X	X	X	X	X	X	X			

TABLE USED TO FIND THE FREQUENCY ACCORDING TO PATIENT WEIGHT IN PEDIATRICS AND NEONATES

		FREQUENCY												
kg	**GENDER**	**16**	**17**	**18**	**19**	**20**	**22**	**25**	**27**	**30**	**35**	**40**	**45**	**50**
8				X	X	X	X	X	X	X	X	X	X	X
8.5				X	X	X	X	X	X	X	X	X	X	X
9		X	X	X	X	X	X	X	X	X	X	X		
9.5		X	X	X	X	X	X	X	X	X	X	X		
10		X	X	X	X	X	X	X	X	X				
11		X	X	X	X	X	X	X	X	X				
12		X	X	X	X	X	X	X	X	X				
13		X	X	X	X	X	X	X	X	X				
14		X	X	X	X	X	X	X	X	X				
15		X	X	X	X	X	X	X	X	X				
20	M	X	X	X	X	X	X	X	X	X				
20	F	X	X	X	X	X	X	X	X	X				
25	N	X	X	X	X	X	X	X	X	X				
25	F	X	X	X	X	X	X	X	X	X				
30	M	X	X	X	X	X	X	X	X	X				
30	F	X	X	X	X	X	X	X	X	X				
35	M	X	X	X	X	X	X	X						

WARRANTY

Equipment LEISTUNG brand PR4-g model

Series No. ..... **ANVISA No.**.**80203470005**

Purchased by:.....

Purchase date:.....

Chit No:.....

This equipment is guaranteed for 12 (twelve) months after purchase date, where the factory is responsible for any defect or manufacturing failure.

The conditions for use, installation and maintenance necessary for this equipment must be followed, respecting technical specifications and installation according to user manual.

This warranty is annulled when:

a) The equipment identification label was modified or removed;

b) The installation of the equipment was not performed according to instruction manual;

c) If is discovered that the damages were caused by bad electrical installation, floating or voltage differences which the equipment works with;

d) Damages due to hit or accidents of any type after purchase;

e) If is discovered intervention of any other person but technical service of LEISTUNG EQUIPAMENTOS LTDA.

The installation of the equipment is responsibility of the buyer.

LEISTUNG EQUIPAMENTOS LTDA. is not responsible for bad installation and use of the equipment.